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EXAMINER

KRUSE, DAVID H

ART UNIT PAPER NUMBER

1638

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/541,346

Applicant(s)

CERNY ET AL.

Examiner

David H. Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-34 is/are pending in the application.
- 4a) Of the above claim(s) 7-9, 12-15, 17, 18 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10, 11, 16, 19 and 21-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/5/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-6, 10, 11, 16 and 19 (corresponding to claims 10, 11, 16, 19 and new claims 22-34) in the reply filed on 21 March 2006 is acknowledged. The traversal is on the ground(s) that the claims have unity of invention because they all relate to the novel and inventive cotton event MON 88913 (page 9 of the Response). This is not found persuasive because the primers of Group II and the detection kit of Group III do not require the cotton seed or plant of Group I, and in fact can be used to confirm that a cotton plant or seed does not in fact comprise event MON 88913.

The Examiner confirms Applicant's statement that the previous Office action contained an error by omitting reference to pending claim 20 (page 8, 1st paragraph of the Remarks). The Examiner notes that claim 20 depends from claim 12 and would be encompassed by Group III of the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 7-9, 12-15, 17, 18 and 20 are withdrawn from further consideration pursuant to 37 CFR § 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 21 March 2006.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one

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claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 10, 11, 19, 24, 30, 33 and 34 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10, 11, 19, 24, 30, 33 and 34 are indefinite because the limitation "cotton event MON 88913" is not an art-recognized characteristic of a cotton plant. Hence, the metes and bounds of the claims are unclear.

6. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 16 and 22-34 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims any glyphosate tolerant cotton plant comprising SEQ ID NO: 1 and 2, and methods of using same.

Applicant describes cotton event MON 88913, representative seed having been deposited under ATCC Accession Number PTA-4854, and progeny thereof comprising cotton event MON 88913.

Applicant does not describe other glyphosate tolerant cotton plants comprising SEQ ID NO: 1 and 2 as broadly claimed.

Hence it is unclear that Applicant was in possession of the invention as broadly claimed.

See *In re Wallach*, 71 USPQ2d 1939 (CA FC 2004), at 1940: Claims in application directed to isolated DNA molecules encoding proteins that inhibit cytotoxic effects of tumor necrosis factor were properly rejected for failure to satisfy written description requirement of 35 U.S.C. § 112, since applicants claimed nucleic acids encoding protein for which they provided only partial sequence, and without approximately 95 percent of amino acid sequence that applicants did not disclose, it cannot be held that DNA molecules claimed in application have been described, since applicants' contention that they were in physical possession of protein does not establish their knowledge of that protein's amino acid sequence or any of its other descriptive properties, even though amino acid sequence is inherent property of protein, and since application does not provide adequate functional description, in that, with only partial amino acid sequence disclosed, chemical structure of nucleic acid molecules that can serve function of encoding protein's amino acid sequence cannot be determined. While a description of a representative number of species is adequate to represent an

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entire genus, wherein there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus (see MPEP 2163).

A method is not described if products used in the method are not described. See 64 Fed. Reg. 71427, 71428 (1999), comment No. 4.

8. Claims 10, 11, 19, 24, 30, 33 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel plants. Since the plant is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 USC § 112 may be satisfied by a deposit of the plant. A deposit of 2500 seeds of each of the claimed embodiments is considered sufficient to ensure public availability. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. It is noted that applicants have deposited the plant but there is no indication in the specification as to public availability.

(a) If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that all restrictions imposed by the depositor

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on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent, would satisfy the deposit requirement made herein (see 37 CFR § 1.808).

(b) If the deposit was not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (i) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (ii) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (iii) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (iv) a test of the viability of the biological material at the time of deposit (see 37 CFR § 1.807); and,
- (v) the deposit will be replaced if it should ever become inviable.

9. Claims 16 and 22-34 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for progeny of deposited cotton plant PTA-4854 comprising the cotton event MON 88913, does not reasonably provide enablement for any glyphosate tolerant cotton plant comprising SEQ ID NO: 1 and 2, or

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methods of using same. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant claims any glyphosate tolerant cotton plant comprising SEQ ID NO: 1 and 2, and methods of using same.

Applicant teaches cotton event MON 88913, representative seed having been deposited under ATCC Accession Number PTA-4854, and progeny thereof comprising cotton event MON 88913.

Applicant does not teach other glyphosate tolerant cotton plants comprising SEQ ID NO: 1 and 2 as broadly claimed.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Those of skill in the instant art recognize that the introduction and integration of a transgene into a plant genome involves some random events, it is unpredictable where in the genome a transgene will become inserted and "events" are random events and generally cannot be duplicated without undue trial and error experimentation. The

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transgene of cotton event MON 88913 is the *aroA* gene that encodes an EPSPS enzyme that is tolerant to glyphosate. The instant claims are directed to transgenic cotton plants comprising any inserted transgene that would produce glyphosate tolerance. The specification does not provide guidance on other transgenes useful for producing glyphosate tolerant cotton within the full scope of the instant claims. The specification does not provide guidance on how to make and use cotton plants comprising transgenes for glyphosate tolerance by inserting said transgenes into a cotton genome between nucleotides having the sequence of SEQ ID NO: 1 and 2 without undue trial and error experimentation.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. § 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. § 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. § 102(e)).

11. Claims 21-27 are rejected under 35 U.S.C. § 102(e) as being anticipated by Anderson *et al* (U.S. Patent 6,573,437 published 3 June 2003, and filed 14 September 1993) taken with the evidence of DOW Agrosiences LLC "Agronomic assessment and seed increase of GM cotton expressing insecticidal genes from *Bacillus thuringiensis*" Application for License DIR 040/2003 November 2003 (Appendix 2, page 25, item 115).

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Applicant defines a part of a cotton plant to include lint (i.e. cotton fibers) on page 17, 3rd paragraph of the specification.

The evidence in the DIR 040/2003 document discloses that since cotton lint contains no DNA or protein, and fiber characteristics of a transgenic cotton plant are the same as non-GM cotton (see page 25 item 115).

Anderson *et al* disclose a transformed cotton plant comprising a DNA encoding a mutant *aroA* gene at claim 7. Anderson *et al* inherently disclose lint produced from such a transformed cotton plant that would be indistinguishable from the lint or "part thereof" of the claimed cotton plant of the instant claims. Hence Anderson *et al* have previously disclosed the claim limitations. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 16 and 22-34 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Anderson *et al* (U.S. Patent 6,573,437 published 3 June 2003, and filed 14 September 1993).

The teachings of Anderson *et al* are outlined above.

Anderson *et al* do not specifically teach SEQ ID NO: 1-4.

The Examiner notes that SEQ ID NO: 1 and 2 are short primers containing short sequences of cotton genomic and transgene sequences, and SEQ ID NO: 3 and 4 contain sequences of cotton genomic and transgene DNA. The transgene sequences taught in SEQ ID NO: 3 and 4 are from a Fig Mosaic Virus promoter known in the art (SEQ ID NO: 3) and an E9 terminator sequence known in the art (SEQ ID NO: 4).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to make glyphosate tolerant transgenic cotton plants comprising a DNA sequence encoding a mutant EPSPS gene as taught by Anderson *et al*. The prior art promoter and terminator sequences would not have led to a teaching of unexpected results, especially since neither sequence defines a glyphosate tolerant transgenic cotton plant. Given the teachings of Anderson *et al*, one of ordinary skill in the art at the time of Applicant's invention would have had a reasonable expectation of success in making a glyphosate tolerant transgenic cotton plant comprising an *aroA* mutant gene.

Conclusion

14. Claims 10, 11 and 19 are free of the prior art, which neither teaches nor anticipates a cotton plant comprising cotton event MON 88913.
15. No claims are allowed.

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16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER



David H. Kruse, Ph.D.
30 May 2006

17. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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